REMARKS

Claims 1-24 have been cancelled, without prejudice. Claims 25-31 are pending.

Claim 25 has been amended to recite "[a] method of prevention of pathologies associated with androgen signaling, which comprises administering to a subject (mammal or non-mammal, human or pet including birds and fish, or mammal or non-mammal farm animal) in need of such prophylaxis an effective amount of lycopene." Support for this amendment is found in, for example, original claim 25, and in the specification at, for example, page 1, lines 1-14. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01 (o) and (l).

Claim 30 has been amended to recite "[a] method of preventing non-cancerous symptoms and/or pathologies sensitive to lycopene which comprises administering to a mammal, mammal or non-mammal pets including birds and fish, or mammal or non-mammal farm animal in need of such prophylaxis an amount of lycopene which leads to a reduction of androgen signaling." Support for this amendment is found in, for example, original claim 25, and in the specification at, for example, page 1, lines 1-14. (*Id.*).

It is submitted that no new matter has been introduced by the foregoing amendments.

§112, First Paragraph Rejection:

Enablement

Claim 25 has been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20070828 at 2). In making the rejection, the Examiner

acknowledged that the specification is "enabl[ing] for a method of treatment of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy an effective amount of lycopene, ..." (*Id.*).

The Examiner, however, asserted that the specification "does not enable any person skilled in the art to prepare a method of prevention of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene." (*Id.*).

The Examiner further asserted that "***the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement*** than the instantly disclosed invention." (*Id.* at 3) (emphasis added).

The Examiner also asserted that "Applicant has ***only*** demonstrated in the experiment section on pages 13-14 of the specification, a method of treatment of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy an effective amount of lycopene." (*Id.*) (emphasis added).

Initially we note, it is the Examiner's burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry his/her burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. It is

well established that claims must be separately analyzed. *Ex parte Jochim*, 11 USPQ2d 561 (BPAI 1988).

The rejection, however, completely fails to identify or articulate any factual basis or supporting evidence to establish that undue experimentation is required to practice the invention. The Examiner asserted only that "***the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement*** than the instantly disclosed invention." (Paper No. 20070828 at 3) (emphasis added). The Examiner's assertion is an incorrect statement of the law and is against the Board's own precedent. *See Ex parte Stamler*, 2003 WL 23012148, *4 (BPAI 2003) (unpublished). The Board in *Stamler* has already addressed and settled this issue by reversing a rejection based on the same premise. In *Stamler*, the Board stated:

> The examiner construed the claimed "method of ... preventing cardiovascular disorders" to "requir[e] the ***absolute*** and complete elimination of any cardiovascular disorders." Examiner's Answer, page 5. Appellants argue that this construction is "improper and not supported by any rule or law." Appeal Brief, pages 12-13.
>
> ***We agree with Appellants that the examiner erred in construing the claim language. The examiner's interpretation of prevention to require "absolute and complete" prevention is unreasonable. The examiner has cited no dictionary definition, scientific treatise, or case law as the basis for interpreting a "method of preventing" disease to require "absolute and complete" prevention of the disease.***
>
> Claim language must be interpreted in light of the specification. See In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983) ("[C]laim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art."). Here, the specification

> states that "S-nitroso-immunoglobulin compounds derived from the nitrosylation of immunoglobulins ... exert vasodilatory and platelet inhibitory effect. Thus, these compounds may be administered as therapeutic agents, to an animal, to promote vasodilation and platelet inhibition, and to treat or prevent cardiovascular disorders." Page 19. Thus, read in light of the specification, the claimed "method of ... preventing cardiovascular disorders" is properly interpreted to mean that the claimed method causes vasodilation and inhibition of platelet aggregation, thereby preventing cardiovascular disorders. ***That is, the claimed method results in vasodilation and inhibition of platelet aggregation, and these effects reduce the risk of, i.e., "prevent," cardiovascular disorders***.
>
> The specification provides evidence that the claimed method results in vasodilation and inhibition of platelet aggregation. See page 50. The examiner has presented no evidence to the contrary. Therefore, the rejection for nonenablement is not supported by a preponderance of the evidence. ***The rejection is reversed.*** [*Id.* at 4-5 (emphasis added)].
>
> For this reason alone, the rejection should be withdrawn.

Furthermore, the Examiner failed to present any evidence or reasoning why this erroneous assertion is relevant to enablement. There is no evaluation of what one skilled in this art would have understood from what is disclosed in the Specification. Moreover, there is no attempt to even define what the level of skill in the art was. At bottom, the Examiner's observation, without more, is an impermissible attempt to shift the burden to the Applicant to positively establish enablement.

As is well known, burden-shifting of this kind is not allowed. "In order to make a rejection, ***the examiner has the initial burden*** to establish a reasonable basis to question the enablement provided for the claimed invention.... ***[T]he minimal requirement is for the examiner to give reasons*** for the uncertainty of the enablement. ***This standard is applicable even when there is no evidence in the***

record of operability without undue experimentation beyond the disclosed embodiments." MPEP § 2164.04 (8th ed. Rev. 5, August 2006, p. 2100-191) (emphasis added). The Examiner's erroneous assertion that "***the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement*** ..." fails to satisfy the Examiner's burden and is ***simply*** not the correct legal standard. (Paper No. 20070828 at 3) (emphasis added). Thus, the rejection falls short of the kind of analysis and evidence required to establish a *prima facie* case for lack of enablement. For this reason also, the rejection should be withdrawn.

Moreover, the Examiner has misinterpreted the scope of the claims by stating that the term "prevention" is "***an absolute definition which means to stop from occurring***." (Paper No. 20070828 at 2). Rather, the claimed method of prevention simply results in reducing the risk of, *i.e.*, "preventing," pathologies associated with androgen signaling. (*See, e.g.*, Specification at page 1, lines 1-14).

Thus, because the Examiner misinterpreted the scope of the claims, the rejection must be withdrawn for this additional reason. The MPEP commands it.

> Before any analysis of enablement can occur, it is necessary for the examiner to construe the claims. For terms that are not well-known in the art, or for terms that could have more than one meaning, it is necessary that the examiner select the definition that he/she intends to use when examining the application, based on his/her understanding of what applicant intends it to mean, and explicitly set forth the meaning of the term and the scope of the claim when writing an Office action. MPEP § 2164.04 (8th Ed., Rev. 5, Aug. 2006, p. 2100-191) *citing Genentech v. Wellcome Foundation*, 29 F.3d 1555, 1563-64, 31 USPQ2d 1161, 1167-68 (Fed. Cir. 1994).

And, the Board's own decisions demand it. *Ex parte Kosley*, 2002 WL 130548, *5-7 (BPAI 2002) (unpublished) (reversing an examiner's enablement rejection because the examiner improperly construed appellants' claims); *Ex parte Schoemaker*, 2003 WL 21280014, *3-4 (BPAI 2003) (unpublished) (stating "the examiner erred in construing the claims" and reversing "the rejection for non-enablement because the specification is presumed to be enabling and the examiner has not presented sufficient evidence or scientific reasoning to support a conclusion to the contrary"); *Ex parte Miles*, 2004 WL 318773, *4 (BPAI 2004) (unpublished) (vacating examiner's rejections under 35 U.S.C. § 112, first and second paragraphs, and "encourag[ing] the examiner to take a step back and construe the claimed invention as a person of ordinary skill in the art, using appellants' specification as a guide. After, having the opportunity to properly construe the claimed invention the examiner will be in a better position to determine whether appellants' specification enables the full scope of appellants' claimed invention."); and *Ex Parte Tsunoda*, 2002 WL 31257863, *3 (BPAI 2002) (unpublished) (rejection reversed because examiner misconstrued the appealed independent claim).

We further note that even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. Indeed, it is well recognized that "a patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01 (8th ed. Rev. 5, August 2006, p. 2100-187) *citing In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v.*

American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Here, the Specification contains examples and detailed descriptions of embodiments of the claimed process. In particular, the Specification describes how to prepare and use the claimed method of prevention of pathologies associated with androgen signaling. (*See* Specification at page 2, line 17 to page 14, line 6). Nothing more is required.

In sum, the specification and knowledge in the art provide ample guidance to allow one of skill in the art to practice the claimed invention without undue experimentation. Accordingly, the rejection is factually insufficient to support a rejection for lack of enablement, and for this reason also, the rejection should be withdrawn.

For the reasons set forth above, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

Rejection under 35 U.S.C. § 102:

Claim 25 were rejected under 35 USC § 102(e)[1] as anticipated by Lorant *et al.*, U.S. Patent No. 6,623,769 ("Lorant"). (Paper No. 20070828 at 4).

For the reasons set forth below, the rejection, has been rendered moot.

Lorant discloses and claims "[a] method for treating an individual having cutaneous signs of aging caused by expression of proteases in the extracellular matrix comprising administering to said individual an amount of lycopene effective to

[1] We note that Lorant is not a §102(a) prior art reference. We assume the Examiner intended to make the rejection of Lorant under §102(e). If our assumption is wrong, the Examiner is asked to clarify so on the record.

substantially inhibit the expression of said proteases in the extracellular matrix of said individual." (Claim 1).

In making the rejection, the Examiner asserted that "Lorant anticipates the claimed invention because Lorant teaches [that] an effective amount of lycopene is administered to a subject in need thereof ***to treat*** pathologies associated with androgen signaling ***such as acne*** (please note since applicant is claiming the use of lycopene as a prophylactic, the administered of lycopene as a prophylactic to a subject in need thereof would read on treating or preventing any and/or all diseases instead of only treating or preventing the claimed pathologies associated with androgen signaling) (see e.g. entire patent including column 3 lines 5-10)." (Paper No. 20070828 at 4) (emphasis added).

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single ***prior art reference*** and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

Claim 25, as amended, recites "***[a] method of prevention*** of pathologies associated with androgen signaling, which comprises administering to a subject (mammal or non-mammal, human or pet including birds and fish, or mammal or non-mammal farm animal) in need of such prophylaxis an effective amount of lycopene." The Examiner has failed to identify wherein Lorant "***[a] method of prevention*** of pathologies associated with androgen signaling ..." as claimed is disclosed. *Levy*, 17 USPQ2d at 1462.

The Examiner asserted only that "Lorant anticipates the claimed invention because Lorant teaches [that] an effective amount of lycopene is administered to a subject in need thereof ***to treat*** pathologies associated with androgen signaling ***such as acne*** ...." (Paper No. 20070828 at 4). However, Lorant only mentions acne one time and in the context of "treatment" for acne, ***not*** preventing pathologies associated with androgen signaling. (Col. 3, lines 5-10).

Accordingly, Lorant does not disclose each and every element of the claimed invention. For this reason, it is respectfully submitted that the rejection fails to present a *prima facie* case for anticipation and must be withdrawn.

Rejection Under 35 USC § 103:

Claims 25-31 were rejected under 35 USC § 103 as unpatentable over Lorant in view of de Salvert, U.S. Patent No. 5,827,520 ("de Salvert"). (Paper No. 20070828 at 5).

The rejection respectfully is traversed.

Lorant is summarized above.

de Salvert discloses that "[a] vehicle which comprises not more than 10% by weight of water, at least one amphiphilic oil, at least one polyol or polyol derivative selected from the group consisting of C_2-C_4 glycols, ether derivatives of a C_2-C_4 glycol and mixtures thereof, and at least one solvent for oil and water, containing an alcohol functional group." (Col. 2, lines 56-62).

In making the rejection, the Examiner asserted that "Lorant teaches an effective amount of Lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne (see, e.g. entire patent including column 3 lines 5-10)." (Paper No. 20070828 at 5).

The Examiner acknowledged, however, that "Lorant does not expressly teach the combination of lycopene and vitamin c administered to a subject in thereof to treat pathologies associated with androgen signaling such as acne." (*Id.*).

To fill the acknowledged gap, the Examiner relied on de Salvert for "teach[ing that] vitamin c treats pathologies associated with androgen signaling such as acne (see, e.g. column 4 lines 50-55)." (*Id.*).

The Examiner then contended that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredient of vitamin c as taught by De Salvert within Lorant's method teachings because the above combined reference would create the claimed invention of a method of treatment of symptoms or pathologies associated with androgen signaling such as acne which comprises administering to a subject in need of such treatment for therapy an effective amount of the combination of lycopene and vitamin c." (*Id.* at 5-6). The Examiner further contended that "the adjustment of

other conventional working conditions (e.g. the claimed active ingredients within various amounts within the claimed composition's method of use and the amounts and times per day the claimed composition's method is administered), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan." (*Id.* at 6).

With a view towards furthering prosecution, claim 25 has been amended to recite "[a] method of prevention of pathologies associated with androgen signaling, which comprises administering to a subject (mammal or non-mammal, human or pet including birds and fish, or mammal or non-mammal farm animal) in need of such prophylaxis an effective amount of lycopene."

Also, claim 30 has also been amended to recite "[a] method of preventing non-cancerous symptoms and/or pathologies sensitive to lycopene which comprises administering to a mammal, mammal or non-mammal pets including birds and fish, or mammal or non-mammal farm animal in need of such prophylaxis an amount of lycopene which leads to a reduction of androgen signaling."

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and

combine the documents relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (April 30, 2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine should ***"be based on objective evidence of record***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also* Examination Guidelines for Determining Obviousness, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

Respectfully, we submit that the rejection is devoid of *any* evidence - or even argument - in support of the proposed combination. All that is there is the Examiner's ***circular reasoning*** that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredient of vitamin c as taught by De Salvert ... because the above combined reference would create the claimed invention of a method of treatment of symptoms or pathologies associated with androgen signaling ...." (Paper No. 20070828 at 6). This circular reasoning is a classic improper hindsight reconstruction of the claimed subject matter. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that ***the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous***

application of the requirement for a showing of the teaching or motivation to combine prior art references.") (emphasis added). For this reason alone, the rejection should be withdrawn.

What the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosure of Lorant using de Salvert to arrive at the claimed method. As is well settled, an Examiner ***cannot*** establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this additional reason.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so, we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie*

obviousness of a claimed invention, ***all claim limitations must be taught or suggested by the prior art***." MPEP § 2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)) (emphasis added).

Assuming *arguendo* that Lorant is properly combinable with de Salvert, which it is not, such a combination does not produce currently amended claims 25 and 30, from which claims 26-29 and 31 depend, respectively. The Examiner asserted that Lorant discloses that "an effective amount of Lycopene is administered to a subject in need thereof to ***treat*** pathologies associated with androgen signaling such as ***acne*** (see, e.g. entire patent including column 3 lines 5-10)." (Paper No. 20070828 at 5) (emphasis added). However, Lorant only mentions acne one time and in the context of "treatment" for acne, ***not*** preventing pathologies associated with androgen signaling. (Col. 3, lines 5-10). Thus, Lorant either alone or in combination with de Salvert does not disclose or suggest "[a] method of prevention ..." or "[a] method of preventing ..." as recited by currently amended claims 25 and 30, respectively.

Therefore, the rejection, Lorant in view of de Salvert, as asserted by the Examiner, falls short of disclosing or suggesting the currently claimed method. For this reason also, the rejection should be withdrawn.

The rejection is also devoid of any discussion of the dependent claims. Accordingly, the record is devoid of any evidence that the Examiner individually considered the dependent claims. It is axiomatic, however, that a dependent claim is not *per se* unpatentable by a document that allegedly makes unpatentable the base claim. Accordingly, "[e]xaminers are reminded that a dependent claim is directed to a combination including everything recited in the base claim and what is recited in the

dependent claim. ***It is this combination that must be compared with the prior art, exactly as if it were presented as one independent claim.***" MPEP § 608.01(n) (8th ed., Rev. 5, Aug. 2006, pp. 600-91). This the Examiner has not done. Accordingly, the rejection is also both factually and legally deficient as to the dependent claims. For this additional reason, the rejection should be withdrawn as to the dependent claims.

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 5, 2008.

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